STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:	)	
	)	
WALGREENS #04466	)	Complaint No. 2014-007566
Permit No. 006438	)	
3645 Frederick Avenue	)	
St. Joseph, MO 64506		

SETTLEMENT AGREEMENT BETWEEN MISSOURI BOARD OF PHARMACY AND WALGREENS #04466

Come now Walgreens #04466 ("Respondent" or the "Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and

voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the draft Complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 006438, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo[1], for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Walgreens #04466 ("Respondent" or the "Pharmacy") is licensed as a pharmacy under the laws of the State of Missouri, Permit No. 006438. Respondent's permit was at all times relevant herein current and active.

3. Respondent has had multiple violations of Board statutes and regulations over the past few years.

4. Inspector Miller visited the Pharmacy on November 12, 2014, to do a repeat inspection of the Pharmacy.

[1] All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

5. Despite being notified of violations over the preceding years, the Pharmacy continued to be in violation of multiple Missouri pharmacy statutes and regulations.

a. Immunization Protocol Violations

6. During her November 12, 2014, inspection of the Pharmacy, Inspector Miller found that the Pharmacy immunization protocols continued to be incomplete.

7. Missouri law gives a licensed pharmacist the authority to give immunizations, to wit:

> 1. The "practice of pharmacy" means . . . the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by a physician for a specific patient as authorized by rule; . . . §338.010.1, RSMo.

8. However, Missouri law requires very specific requirements to be met in order for pharmacists at the Pharmacy to be authorized to give immunizations. Missouri law provides:

> (1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.
>
> > (A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (12) years of age.
> >
> > (B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirement.
>
> (2) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualification under subsections 4(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines.

(3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.

(4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:

(A) Hold a current unrestricted license to practice pharmacy in this state;

(B) Hold a current cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;

(C) Successfully complete a certificate program in the administration of vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy;

(D) Maintain documentation of the above certifications;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal.

(F) Provide documentation of Subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines

authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing the length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street address of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it and at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning

of implementation to a minimum of eight (8) years after termination of the protocol.

(6) Record Keeping

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection 6(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(D) The records required by this rule shall be maintained securely and confidentially as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the prescription files of the pharmacy. If the vaccine is not being administered on behalf of the pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine; and

2. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the State Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(7) Notification Requirement

(A) A pharmacist administering vaccines authorized by Chapter 338, RSMo, shall notify the authorizing physician within seventy-two (72) hours after administration of the following:

1. The identity of the patient;
2. The identity of the vaccine(s) administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) The pharmacist shall provide a written report to the patient's primary care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.

(C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient's primary care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

(D) A pharmacist administering vaccine(s) shall report the administration to all entities as required by state or federal law.

(E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule. 20 CSR 2220-6.050.

9. The Pharmacy's immunization protocol was deficient because it lacked the date upon which it was signed by the protocol physician in violation of 20 CSR 2220-6.050(5)(B).

b. Medical Prescription Order Violations

10. During her November 12, 2014, inspection of the Pharmacy, Inspector Miller reviewed the Pharmacy's Medical Prescription Order policies and procedures.

11. In order for the Pharmacy to administer by medical prescription order, it must comply with 20 CSR 2220-6.040 which includes the following:

> (4)(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs, including the disposal of used and contaminated supplies and appropriate handling of acute and adverse events. The manual shall be reviewed annually and be available for inspection by the State Board of Pharmacy or authorized representative. 20 CSR 2220-6.040(4)(C).

12. During the inspection, the Pharmacy failed to provide Inspector Miller with documentation of the annual review of the policies and procedures for administration by medical prescription order in violation of 20 CSR 2220-6.040(4)(C).

c. Controlled Substance Violations

13. During her November 12, 2014, inspection of the Pharmacy, Inspector Miller reviewed the controlled substance inventories.

14. An inventory was completed on August 4, 2013, when the Pharmacy's pharmacist-in-charge was changed.

15. The August 4, 2013, inventory did not include an inventory of the over-the-counter pseudoephedrine products.

16. When a pharmacist-in-charge is changed, Missouri law requires:

> (T) When the board-recognized pharmacist-in-charge is changed at the licensed facility, an appropriate documented inventory of controlled substances must be taken. 20 CSR 2220-2.090(2)(T)

17. The controlled substance inventory to be taken when the pharmacist-in-charge is changed includes over-the-counter pseudoephedrine products.

18. By not inventorying pseudoephedrine products in the August 4, 2013, inventory of controlled substances, the Pharmacy was in violation of 20 CSR 2220-2.090(2)(T).

d. Class J Policies and Procedures Incomplete

19. During her November 12, 2014, inspection, Inspector Miller reviewed the policies and procedures for the Pharmacy's Class J Pharmacy Permit.

20. Missouri law requires:

> (1)(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:
>
> 1. A description of how the parties will comply with federal and state laws and regulations;
> 2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;
> 3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;
> 4. The provision of adequate security to protect the confidentiality and integrity of patient information;
> 5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.
>
> 20 CSR 2220-2.650(1)(C).

21. The policies and procedures maintained by the Pharmacy failed to address the maintenance of a quality assurance program as required by statute.

22. The Pharmacy had been given previous warning that this constituted a violation of Missouri law after Inspector Miller's February 27, 2013, Inspection of the Pharmacy.

23. The Pharmacy's failure to maintain a policy and procedure manual with all required information relating to their Class J permit is in violation of 20 CSR 2220-2.650(1)(C).

e. Compounding Violations

24. During her November 12, 2014, inspection of the Pharmacy, Inspector Miller reviewed compounded drug products and found several that did not comply with Missouri law.

25. For compounded drug products, Missouri law requires:

> (7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.
>
> (A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:
> 1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;
> 2. Date of compounding;
> 3. Identity of the compounding pharmacist;
> 4. A listing of the drug products/ingredients and their amounts by weight or volume;
> 5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;
> 6. The identity of the source, lot number and the beyond use date of each drug product/ingredient, as well as an in-house lot number and beyond use date for bulk compounded products; and
> 7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.
>
> * * *
>
> (F) The actual name of each active ingredient or therapeutic ingredient contained in a compound shall be listed on the container of any product provided to a customer. 20 CSR 2220-2.400(7)(A), (F)

26. The Pharmacy was unable to produce its batch compounding log at the time of the inspection.

27. The Pharmacy's failure to produce its batch compounding log at the time of Inspector Miller's inspection is in violation of 20 CSR 2220-2.400(7)(A).

28. Inspector Miller identified at least two compounded products that were labeled as "Magic Mouthwash" and failed to list the active or therapeutic ingredients on the container. Prescription numbers 2451212 and 2433414.

29. Inspector Miller identified at least one compounded product that was labeled as "Baby Butt Paste" and failed to list the active or therapeutic ingredients on the container. Prescription number 2449757.

30. By failing to list the active or therapeutic ingredients on the containers of prescriptions 2451212, 2433414 and 2449757, the Pharmacy was in violation of 20 CSR 2220-2.400(7)(F).

31. The Pharmacy's compounding logs were also incomplete. Some entries lacked a description of the process, ingredient lot number, ingredient expiration dates, and the responsible pharmacist.

32. Incomplete compounding logs are in violation of 20 CSR 2220-2.400(7)(A).

f. Repackaging Violations

33. During her November 12, 2014, inspection of the Pharmacy, Inspector Miller reviewed the repacked drug products prepared by the Pharmacy.

34. Missouri law allows the Pharmacy to repackage drug products, but has specific labeling requirements, to wit:

> (D) Any prepackaged drug must have a label affixed to it which contains, at a minimum, the name, strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it

is fully traceable and is readily retrievable during an inspection. 20 CSR 2220-2.130(1)(D).

35. Inspector Miller found drug products in the Pharmacy which failed to meet these labeling requirements in violation of 20 CSR 2220-2.130(1)(D).

g. Failure to Maintain Current Technician List

36. During her November 12, 2014, inspection of the Pharmacy, Inspector Miller reviewed the Pharmacy Technician list.

37. Missouri law requires:

> (2) The responsibilities of a pharmacist in charge, at a minimum, will include:
>
> * * *
>
> (BB) Maintain a current list of all personnel employed by the pharmacy as pharmacy technicians. The list shall include the name, registration number or a copy of an application for registration that has been submitted to the board and a description of duties to be performed by each person contained on the list. 20 CSR 2220-2.090(2)(BB)

38. By failing to maintain a current pharmacy technician list, the Pharmacy was in violation of 20 CSR 2220-2.090(2)(BB).

h. Failure to offer patient counseling

39. During her November 12, 2014, inspection of the Pharmacy, Inspector Miller observed a failure to offer patient counseling to all patients who picked up their prescriptions. This was observed at the interior counter and at the drive-up window.

40. Missouri law requires:

> (1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern

> under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained . . . 20 CSR 2220-2.190

41. By failing to offer each and every patient of the pharmacy counseling, the Pharmacy was in violation of 20 CSR 2220-2.190.

February 3, 2016 Inspection by Inspector Miller

42. On February 3, 2016, Inspector Miller returned to the Pharmacy to conduct another inspection.

43. During her inspection of the Pharmacy, she found additional violations of Missouri law.

a. Inadequate Labeling on Controlled Substance Prescriptions

44. During her February 3, 2016, inspection of the Pharmacy, Inspector Miller reviewed controlled substance prescriptions that were being filled by the Pharmacy.

45. The labeling of controlled substances must comply with Missouri law, to wit:

> 5. Whenever a pharmacist or practitioner sells or dispenses any controlled substance on a prescription issued by a physician, physician assistant, dentist, podiatrist, veterinarian, or advanced practice registered nurse, the pharmacist or practitioner shall affix to the container in which such drug is sold or dispensed a label showing his or her own name and address of the pharmacy or practitioner for whom he or she is lawfully acting; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the physician, physician assistant, dentist, podiatrist, advanced practice registered nurse, or veterinarian by whom the prescription was written; the name of the collaborating physician if the prescription is written by a physician assistant, and such directions as may be stated on the prescription. No person shall alter, deface, or remove any label so affixed. §195.100.5, RSMo.

46. When reviewing the labels of controlled substances filled by the Pharmacy, Inspector Miller found that the name of the collaborating physician was not on the label of controlled substance prescriptions written by nurse practitioners or physician assistants.

47. By failing to include the collaborating physician's name on the label, the Pharmacy was in violation of §195.100.5, RSMo.

b. Inability to Access OTC Pseudoephedrine Sales Records

48. During her February 3, 2016, inspection of the Pharmacy, Inspector Miller requested access to the Pharmacy's over-the-counter pseudoephedrine sales records.

49. Missouri law requires the Pharmacy to maintain open access to those records, to wit:

> 1. Access to the database and controlled substance records shall be made available to those agencies with authority under Chapter 195 and Chapter 338, RSMo. 19 CSR 30-1.074(3)(N)(1).

50. By failing to provide access to Inspector Miller to the over-the-counter pseudoephedrine sales records through the database maintained by the Department of Health and Senior Services, the Pharmacy was in violation of 19 CSR 30-1.074(3)(N)(1).

c. Compounding Violations

51. During her February 3, 2016, inspection of the Pharmacy, Inspector Miller reviewed the compounding log for compounded drug products and found that it did not comply with Missouri law.

52. For compounded drug products, Missouri law requires:

> (7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.
>
> (A) Such methods shall include the following and shall be followed in the execution of the drug compounding process. A separate log shall be maintained which includes:
> 1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;
> 2. Date of compounding;
> 3. Identity of the compounding pharmacist;

4. A listing of the drug products/ingredients and their amounts by weight or volume;
5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;
6. The identity of the source, lot number and the beyond use date of each drug product/ingredient, as well as an in-house lot number and beyond use date for bulk compounded products; and
7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed. . . .20 CSR 2220-2.400(7)(A), (F)

53. The Pharmacy was unable to produce its batch compounding log at the time of the inspection.

54. The Pharmacy's failure to produce its batch compounding log at the time of Inspector Miller's inspection is in violation of 20 CSR 2220-2.400(7)(A).

d. Generic Substitution Not Authorized

55. During her February 3, 2016, inspection of the Pharmacy, Inspector Miller reviewed prescriptions that had been filled by the Pharmacy.

56. Inspector Miller found prescription number 2601293 had been filled with a generic form of the prescribed drug without authorization from the prescriber.

57. Missouri law allows pharmacists to substitute generic drugs for brand name drugs only under certain circumstances, to wit:

> 2. A pharmacist who receives a prescription for a brand name drug may, unless requested otherwise by the purchaser, select a less expensive generically equivalent product under the following circumstances:
>
> (1) If a written prescription is involved, the prescription form shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words: "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without

> the signature of the prescriber on one of these lines." §338.056.2(1).

58. There was no authorization to submit a generic for the prescribed drug on prescription 2601293.

59. By substituting a generic drug product without authorization, the Pharmacy was in violation of section 338.056.2(1), RSMo.

e. Repackaging Violations

60. During her February 3, 2016, inspection of the Pharmacy, Inspector Miller reviewed the repacked drug products prepared by the Pharmacy.

61. Missouri law allows the Pharmacy to repackage drug products but has specific labeling requirements, to wit:

> (D) Any prepackaged drug must have a label affixed to it which contains, at a minimum, the name, strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection. 20 CSR 2220-2.130(1)(D).

62. Inspector Miller found that some cells in the repackaging robot failed to contain the lot number and expiration date of the repackaged drugs in violation of 20 CSR 2220-2.130(1)(D).

f. Outdated Drug Products in Active Inventory

63. During her February 3, 2016, inspection of the Pharmacy, Inspector Miller reviewed the active inventory of the Pharmacy.

64. Inspector Miller found at least seven expired drug products in active inventory.

65. Missouri law requires:

> (V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items. 20 CSR 2220-2.090(2)(V).

66. By failing to keep expired drug products out of the active inventory at the Pharmacy, it was in violation of 20 CSR 2220-2.090(2)(V).

g. Failure to Maintain Pharmacy in Sanitary Condition

67. During her February 3, 2016, inspection of the Pharmacy, Inspector Miller found a reconstitube tip near the sink in the Pharmacy.

68. Use of this tip could cause cross contamination of drug products.

69. Missouri law requires:

> (F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions. 20 CSR 2220-2.010(1)(F).

70. Leaving a reconstitube tip near the sink of the Pharmacy was not clean or sanitary and was in violation of 20 CSR 2220-2.010(1)(F).

JOINT CONCLUSIONS OF LAW

71. Cause exists for Petitioner to take disciplinary action against Respondent's permit to practice pharmacy for its violation of §338.210.5, which provides:

> 5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

72. Further cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit pursuant to 20 CSR 2220-2.010(1)(O), which states:

(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

73. Respondent's conduct is cause for disciplinary action against its permit to operate a pharmacy under §338.055 RSMo, which provides:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
>
> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government; §338.055.2(6) and (15), RSMo.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo (2000):

A. Respondent's pharmacy permit number 006438 shall be placed on **PROBATION for a period of THREE (3) YEARS.** The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

The following terms apply for the entire disciplinary period.

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.

4. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

6. Respondent shall not serve as an intern training facility for interns.

7. The Permit Holder must establish a two-hour pharmacist-in-charge ("PIC") concentrated compliance training program to be completed by any PIC employed at this Pharmacy store (#04466). The PIC compliance training program must be approved by the Board and must include training on Missouri's pharmacy compliance requirements, including, but not limited to, recordkeeping and record retrieval policies and procedures, Missouri's immunization requirements and 20 CSR 2220-2.090. The PIC employed at this Pharmacy shall complete the Board-approved training program(s) within ninety (90) days of the effective date of this Agreement, or within 90 days of the date on which the Board approves the training program, whichever is later. Training may be provided over multiple days and/or on a group basis. Walgreens shall notify the Board office in writing within sixty (60) days of this Agreement, or within sixty (60) days of the Board's approval of the training program, whichever is later, of the training date(s), time(s) and location(s). A Board inspector shall be allowed to attend and present information during the required training program(s) upon request. Walgreens shall maintain documentation of the PIC training date(s) in the pharmacy's records; the required documentation must be produced on inspection or at the request of the Board. If the PIC changes and the new PIC has not completed the training program, the new PIC shall be required to complete the Board approved training program within ninety (90) days after being designated PIC, or within 90

days of the Board's approval of the training program, if not approved at the time he or she became the new PIC, whichever is later. Walgreens #04466 shall maintain documentation of its PIC's training date(s), with its applicable pharmacy records. The required documentation must be produced on inspection, or at the request of the Board.

8. Within thirty (30) days of the effective date of this agreement, Walgreens shall designate and provide the PIC specific time periods each week to review pharmacy operations and compliance. These periods shall not be shorter than two (2) hours. The designated days and allowed time frame must be documented, and available for review by a Board inspector. During this dedicated time, the PIC will not be required to be involved in dispensing or administration activities.

9. Respondent shall select a pharmacist consultant for the purpose of reviewing and insuring the pharmacy's compliance with all applicable laws and regulations. The consultant shall be a Missouri licensed pharmacist whose license is current and not subject to disciplinary action by the Board. The consultant may be an employee of Walgreens. The consultant shall not be employed by, assigned to, or have worked for Walgreens #04466, in the past six (6) months. The consultant shall not be a member of Walgreens management or the PIC for Walgreens #04466. Within thirty (30) days of the beginning of probation, Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval. Within thirty (30) days of the beginning of probation the said consultant shall visit the pharmacy, evaluate and provide corrective actions to remedy the issues outlined in this agreement, conduct a review for compliance with all applicable laws and regulations using the Board's Pharmacy Self-Assessment Form, and submit a written report to the Board office within thirty (30) days of the visit. The consultant's report shall include the suggested corrective actions, a timeline for the pharmacy to complete such corrective actions, items/areas reviewed for compliance with applicable laws and regulations during the visit, any deficiencies noted, and a plan to correct any deficiencies noted. The consultant shall then conduct similar visits and provide ongoing reports to the Board office on a three (3) month cycle for the first two years of the probationary period and on a six (6) month cycle thereafter for the remainder of the probationary period. All consultant reports are due at the Board office within thirty (30) days of the consultant's visit to the pharmacy. The consultant shall be hired at Respondent's expense.

10. In addition to the required PIC training program, the current PIC for Walgreens #04466 and any subsequent PIC for the pharmacy must review the Board Inspection reports for the previous seven (7) years. The PIC for Walgreens #04466 must also complete the Board's Pharmacy Self-Assessment Guide along with, and in the physical presence of, the pharmacy's District Manager or the Board approved Internal Consultant. The Pharmacy's Self-Assessment Guide must be completed before January 15th and July 15th of each year during the probationary period. The Completed Self-Assessment Guide must be documented

in writing and maintained in the pharmacy's records. All records must be produced on inspection or at the request of the Board.

11. To ensure compliance, the following self-inspections shall be required each year during the probationary period for Walgreens # 04466:

a. Respondent's District Manager shall conduct monthly self-inspections of the pharmacy on or before the 15th of each month. After the first two (2) years of probation, the Respondent's District Manager shall conduct bi-monthly self-inspections of the pharmacy, alternating each month with the Respondent's Healthcare Supervisor.

b. Respondent's Healthcare Supervisor shall perform a monthly self-inspection of the pharmacy on or before the last day of each month, provided the self-inspection must be completed after the District Manager's required monthly inspection. After the first two (2) years of probation, the Respondent's Healthcare Supervisor shall conduct bi-monthly self-inspections of the pharmacy, alternating each month with the Respondent's District Manager.

c. Respondent's store manager shall conduct quarterly self-inspections of the pharmacy on or before January 15th, April 15th, July 15th, and October 15th of each year during the probationary period.

d. Respondent's PIC shall conduct bi-annual self-inspections on or before January 15 and July 15 of each year.

e. All self-inspections required by this Order/Settlement Agreement shall be completed using the Board's Pharmacy Self-Assessment Guide. The Completed Self-Assessment Guide must be documented in writing and maintained in the pharmacy's records. All records must be produced on inspection or at the request of the Board.

12. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

13. All required prescription records and records relating to immunizations or medication administered by medical prescription order shall be produced on inspection or at the request of the Board.

14. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

15. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said discipline, Respondent's permit as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

C. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

E. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement

Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____REQUESTS

__X__DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE AS A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's permit and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's permit. Effective

fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's permit, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

WALGREENS PHARMACY
#04466

By: _____

As authorized representative for
Walgreens Pharmacy #04466

Printed: Rina Shah

Date: 10/15/18

PETITIONER

MISSOURI BOARD OF
PHARMACY

By: _____
Kimberly Grinston
Executive Director

Date: 11.19.18

NEWMAN, COMLEY & RUTH P.C.

By: _____
Alicja Embley Turner #48675
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Tel: (573) 634-2266
Fax: (573) 636-3306
turnera@ncrpc.com

Attorneys for Petitioner